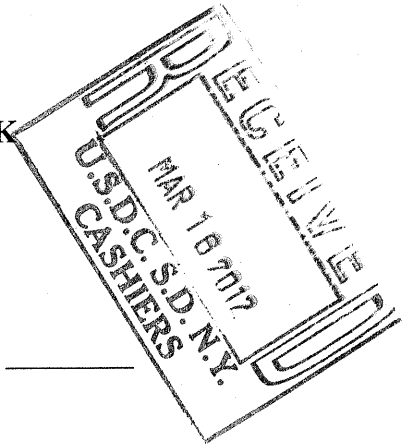


12 MISC 00084

UNITED STATES DISTRICT COURT
FOR THE
SOUTHERN DISTRICT OF NEW YORK



In the Matter of the Application of Petitioner,
SHIRE HUMAN GENETIC THERAPIES, INC.)
for an Order Pursuant to 28 U.S.C. § 1782 to)
Take Discovery, Pursuant to the Federal Rules of)
Civil Procedure, of Respondent MOUNT SINAI)
SCHOOL OF MEDICINE and its employees,)
ROBERT J. DESNICK, YIANNIS A. IOANNOU,)
and DAVID F. BISHOP, For Use In Foreign)
Proceedings)

Misc. No. _____

APPLICATION FOR DISCOVERY IN AID OF FOREIGN LITIGATION
PURSUANT TO 28 U.S.C. § 1782

Shire Human Genetic Therapies, Inc.

By its attorneys,

Of counsel:

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I. INTRODUCTION

Petitioner Shire Human Genetic Therapies, Inc. (“Shire HGT”) makes this application for an order pursuant to 28 U.S.C. § 1782 authorizing its attorneys to issue and serve the subpoenas attached hereto as Exhibit A, pursuant to Rule 45 of the Federal Rules of Civil Procedure, upon Respondents Mount Sinai School of Medicine (“Mt. Sinai”) and its current employees, Professors Robert J. Desnick, Yiannis A. Ioannou and David F. Bishop, to present testimony for use in an Opposition proceeding initiated by Shire HGT against Mt. Sinai’s European Patent No. EP 1 942 189 B1 (“EP 189 patent”) and currently pending in the European Patent Office (“EPO proceeding”).¹ Professors Desnick, Ioannou and Bishop are the named inventors of the EP 189 patent. Shire HGT seeks their depositions regarding the validity, scope and sufficiency of the EP 189 patent, including but not limited to the structure of the α -galactosidase A isoforms (the subject matter of the EP 189 patent) that have been isolated from blood plasma and various other sources in the prior art.

II. JURISDICTION

This court has subject matter jurisdiction under 28 U.S.C. § 1331 because this matter arises under the laws of the United States, namely, 28 U.S.C. § 1782.

III. VENUE

Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Mt. Sinai resides in this judicial District and each of Professors Desnick, Ioannou, and Bishop are employed by Mt. Sinai and have offices in this District.

¹ Shire Deutschland GmbH and Shire Human Genetic Therapies AB also may seek to use the requested discovery in the following additional foreign proceedings that also involve the EP 189 patent: (1) a patent infringement proceeding initiated by Mt. Sinai against Shire Deutschland GmbH in the District Court of Mannheim, now pending appeal in the Karlsruhe Court of Appeal; and (2) an infringement and invalidation proceeding involving Mt. Sinai and Shire Human Genetic Therapies AB in the Stockholm District Court.

IV. PARTIES

A. SHIRE HGT

Shire HGT is a biopharmaceutical company located at 300 Shire Way in Lexington, Massachusetts. Shire HGT manufactures and sells Replagal®, a lifesaving enzyme replacement therapy used for the treatment of the rare lysosomal storage disease known as Fabry disease. The active ingredient in Replagal® is a gene-activation produced enzyme known as alpha galactosidase A.

B. THE RESPONDENTS

Mt. Sinai is a medical research and academic institution in the United States, having an office in this District at 1425 Madison Avenue, New York, New York. Mt. Sinai is listed as the Proprietor on the EP 189 patent entitled “Method for Producing Secreted Proteins,” issued on April 14, 2010, and related to a secreted human α -galactosidase used for the treatment of Fabry disease. Professors Robert J. Desnick, Yiannis A. Ioannou and David F. Bishop are the named inventors of Mt. Sinai’s EP 189 patent, are currently employed at Mt. Sinai, and have offices at 1425 Madison Avenue, New York, New York.

V. BACKGROUND

A summary of the relevant proceedings is set forth below.

A. THE GERMAN INFRINGEMENT PROCEEDING

On April 14, 2010, the same day its EP 189 patent issued, Mt. Sinai filed an infringement action against Shire Deutschland GmbH and its five managing directors in the District Court of Mannheim, alleging that its sale of Replagal® in Germany infringes the EP 189 patent (the

“German Action”). On January 18, 2011, the District Court Manheim, 2nd Civil Chamber, issued its decision in that action. That decision is currently on appeal.²

B. THE SWEDISH PROCEEDING

On April 14, 2010, Mt. Sinai also filed an infringement action against Shire Human Genetic Therapies AB in the Stockholm District Court, similarly alleging that its sale of Replagal[®] in Sweden infringes the EP 189 patent (the “Swedish Action”). On March 30, 2011, Shire Human Genetic Therapies AB filed an action for invalidation of the EP 189 patent to be heard jointly with the infringement action. The Swedish Action remains pending.

C. THE EPO OPPOSITION PROCEEDING

On July 23, 2010, Shire HGT initiated an Opposition in the European Patent Office to revoke the EP 189 patent in its entirety (the “EPO proceeding”). *See* Declaration of Albrecht von Menges (“Menges Decl.”), filed herewith, ¶ 4; Declaration of Margaret E. Ives, filed herewith, Ex. 1. A primary basis for revocation of the EP 189 patent asserted by Shire HGT in the EPO proceeding is that certain prior art mixtures of α -galactosidase A isoforms isolated from human plasma inherently include the particular isoform claimed in the EP 189 patent. *Id.* An oral hearing is set for July 17, 2012. Menges Decl., ¶ 8. The final deadline for making submissions to the EPO is May 17, 2012. *Id.*

² On December 2, 2010, Shire Deutschland GmbH filed a Section 1782 application in this Court seeking limited discovery from Mt. Sinai (namely, an unredacted copy of an exclusive license agreement between Mt. Sinai and Genzyme related to the ownership of the EP 189 patent) to be used in the German infringement proceeding. On December 9, 2010, this Court (Scheindlin, J.) denied that application, finding primarily that (1) the German Court could have ordered Mt. Sinai to produce the unredacted agreement had Shire formally moved for such production; and (2) Shire had not demonstrated a substantial need for the detailed commercial information contained in the unredacted Agreement. That application and this Court’s subsequent decision are unrelated to this application by which Shire seeks depositions of the EP 189 patent inventors in this District.

VI. ARGUMENT

A. SECTION 1782

Pursuant to 28 U.S.C. § 1782(a), “[t]he district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal. . . upon the application of any interested person.” 28 U.S.C. § 1782. Here, Shire HGT easily satisfies the three basic requirements for relief under the statute: (1) this application is brought in the district court of the district in which respondents Mt. Sinai and its employees reside or are found – *i.e.*, this District; (2) the requested discovery is “for use in a proceeding in a foreign or international tribunal” – the EPO proceeding and/or the German and Swedish Actions; and (3) Shire HGT is a party to the EPO proceeding and, therefore, is an “interested person.”

According to the Supreme Court, district courts may also weigh the following additional discretionary factors before granting a § 1782 request: (1) whether the person from whom discovery is sought is a participant in the foreign proceeding”; (2) “the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U. S. federal-court judicial assistance”; (3) “whether the § 1782(a) request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States”; and (4) whether the discovery requests are “unduly intrusive or burdensome.” *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 264-65 (2004). In assessing these factors and generally reviewing the § 1782 application, district courts should be guided by “the twin aims of § 1782: providing efficient means of assistance to participants in international litigation and encouraging foreign countries by example to provide similar means of assistance to our courts.” *In re Gushlak*, 2011

U.S. Dist. LEXIS 91912, *11 (E.D.N.Y. Aug. 17, 2011) (citing *In re Microsoft Corp.*, 428 F. Supp. 2d 188, 193 (S.D.N.Y. 2006); *Schmitz v. Bernstein Liebhard & Lifshitz, LLP*, 376 F.3d 79, 84 (2d Cir. 2004)).

As courts in the Second Circuit have consistently held, “it is far better to provide federal court assistance than none at all.” *Minatec Finance S.A.R.L. v. SI Group, Inc.*, 2008 U.S. Dist. LEXIS 63802, *12 (N.D.N.Y. Aug. 18, 2008); see also *In re Gemeinschaftspraxis Dr. Med. Schottdorf*, 2006 U.S. Dist. LEXIS 94161, *13 (S.D.N.Y. Jan. 4, 2007) (“these considerations counsel heavily in favor of generous federal-court assistance”).

B. SHIRE HGT HAS SATISFIED THE PRIMA FACIE REQUIREMENTS OF SECTION § 1782

As noted above, there can be no real dispute that Shire HGT’s Application satisfies the statutory requirements of Section 1782. First, Mt. Sinai has its principal place of business at 1425 Madison Avenue, New York, New York and is, therefore, “found” in this District. Professors Desnick, Ioannou and Bishop are employed by Mt. Sinai and have offices at 1425 Madison Avenue, New York, New York and are, therefore, also “found” in this District. Second, the requested discovery is for use in a foreign proceeding – namely the EPO proceeding.³ Third, Shire HGT is a named party in the EPO proceeding and, therefore, clearly an “interested person” under the statute. Finally, the discovery sought herein relates directly to the inventions claimed in the EP 189 patent, the subject matter of the relevant foreign proceedings, and is sought in support of Shire HGT’s positions in those proceedings. Thus, the discovery is of the type Section 1782 is designed to facilitate. There can be no question that the information sought in this Application is directly relevant to key issues in the EPO proceeding

³ As set forth above in footnote 1, Shire Deutschland GmbH and Shire Human Genetic Therapies AB may also seek to use the deposition transcripts and exhibits in the respective actions to which they are a party, each also a foreign proceeding.

and, therefore, necessary to assist Shire HGT in that proceeding. *See, e.g., In re Iwasaki Electric Co., Ltd.*, 2005 U.S. Dist. LEXIS 10185, *2-*3 (S.D.N.Y. May 26, 2005), *aff'd by U.S. Philips Corp. v. Iwasaki Elec. Co.*, 142 Fed. Appx. 516 (2d Cir. N.Y. 2005) (unpublished) (noting that, where parties engaged in patent litigation in the U.S., Germany and Japan and depositions had been taken in the U.S., there was “no doubt” that the depositions transcripts were relevant in the foreign proceedings as well).

C. THE INTEL FACTORS FAVOR SHIRE HGT

1. THE EPO LACKS THE ABILITY TO ORDER PRODUCTION

The first discretionary factor a U.S. district court should consider in deciding whether to grant a § 1782 application is whether the party from whom discovery is sought is a party to the foreign proceeding. *Intel*, 542 U.S. at 264. However, courts in this district analyzing this factor focus on “the foreign tribunal's ability to control the evidence and order production, not the nominal target of the § 1782 application.” *In re OOO Promnefstroy*, 2009 U.S. Dist. LEXIS 98610, *15 (S.D.N.Y. Oct. 15, 2009); *cf. Minatec*, 2008 U.S. Dist. LEXIS 63802 at *14-*16 & n. 9 (finding this factor neutral where petitioner sought depositions of current employees of the defendant in the German action and German law was unclear as to whether the German court could compel those individuals’ depositions).

Here, there is no procedure set forth in the European Patent Convention (“EPC”) pursuant to which the EPO could order Mt. Sinai to produce the inventors’ depositions for use in the EPO proceedings. Menges Decl., ¶ 6. Professors Desnick, Ioannou and Bishop are not parties to the EPO action. Moreover, the fact that Mt. Sinai is a party to EPO action is irrelevant, given that the EPO cannot order Mt. Sinai to make Professors Desnick, Ioannou and Bishop available for deposition. Notably, there are no provisions of the EPC which would preclude Shire HGT from

using evidence obtained by U.S. discovery procedures in the EPO proceeding. *Id.*, ¶ 7. This factor is, therefore, at best, neutral.⁴

2. THE REQUESTED DISCOVERY WOULD CLEARLY AID THE EPO IN DECIDING THE ISSUES BEFORE IT

The second factor a district court should consider is “the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign [tribunal] to U.S. federal-court judicial assistance.” *Intel*, 542 U.S. at 264. In this Circuit, courts evaluating this factor “should err on the side of ordering discovery, since foreign courts can easily disregard material they do not wish to consider.” *In re Gushlak*, 2011 U.S. Dist. LEXIS 91912 at *12.

This factor does not require that the materials sought would even be discoverable in the foreign jurisdiction. *Intel*, 542 at 247; see also *In re Gushlak*, 2011 U.S. Dist. LEXIS 91912 at *11 (“In order to be entitled to discovery under § 1782, the applicant is not required to ‘exhaust’ the discovery procedures available in the foreign court. . . . Indeed, the applicant need not show that the material in question would even be discoverable in the foreign court.”) (internal quotations and citations omitted). As at least one court in this Circuit has cautioned, district courts should not assume, just because a foreign country has not adopted discovery procedures that are as extensive as those of the United States, that the foreign tribunal would reject assistance from a United States district court. *Minatec*, 2008 U.S. Dist. LEXIS 63802 at *24 (“even if a foreign tribunal may be too hesitant to order the level of production sought here, this does not mean that there is any resistance to receiving such evidence collected under this statute”). Nor should the court engage in “‘an extensive examination of foreign law’ that would likely lead to a ‘superficial’ ruling based on ‘a battle-by-affidavit of international legal experts.’”

⁴ It is also worth noting that, “[u]ntil *Intel*, the courts within the Second Circuit did not make any distinction between a participant to the foreign litigation and a non-party, and thus the element of being a participant in the foreign litigation did not factor significantly in either denying or granting a § 1782 discovery request.” *Minatec*, 2008 U.S. Dist. LEXIS 63802 at *13, n. 7.

In re Gushlak, 2011 U.S. Dist. LEXIS 91912 at *12 (quoting *Euromepa*, 51 F.3d at 1099).

Rather, in this Circuit, to defeat a § 1782 application, the *opponent* of the § 1782 application must present “‘authoritative proof,’ in the form of ‘judicial, executive, or legislative declarations’ from the forum country” that specifically indicates that the foreign jurisdiction would reject the § 1782 assistance. *Id.*; *OOO Promnefstroy*, 2009 U.S. Dist. LEXIS 98610 at *19-*22.⁵

Here, Shire HGT seeks to depose Professors Desnick, Ioannou, and Bishop regarding the validity, scope and sufficiency of the EP 189 patent, including but not limited to the structure of the α -galactosidase A isoforms that have been isolated from blood plasma and various other sources in the prior art. Because the discovery sought is directly relevant to the ongoing EPO proceeding where the EP 189 patent is directly at issue and there is no statute or case law that would prevent submission of the deposition transcripts to the EPO (*see* Menges Decl., ¶ 7), this factor weighs in favor of granting Shire HGT’s Application.

3. SHIRE HGT BRINGS THIS APPLICATION IN GOOD FAITH

The third factor a district court should consider is “whether the § 1782(a) request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States.” *Intel*, 542 U.S. at 265. Courts within the Second Circuit have suggested that the primary issue district courts should consider in evaluating this factor is whether the petitioner is pursuing the discovery in “bad faith.” *Minatec*, 2008 U.S. Dist. LEXIS 63802 at *26-*27; *In re Gemeinschaftspraxis*, 2006 U.S. Dist. LEXIS 94161 at *25-*26 (S.D.N.Y. Jan. 4, 2007).

⁵ *Compare Schmitz*, 376 F.3d at 84 (upholding district court’s denial of § 1782 request where respondent filed letters from German prosecutor and Ministry of Justice opposing the petition on the grounds that production of the requested discovery would compromise an ongoing criminal investigation and violate the rights of the criminal defendants involved).

Here, Shire HGT has not engaged in bad faith and has not brought this Application for any improper purpose. Rather, Shire HGT brings this Application for the legitimate purpose of seeking narrowly tailored discovery designed to develop evidence directly relevant to contested issues in pending foreign proceedings. Thus, Shire HGT has invoked § 1782 precisely for its intended purpose. In such circumstances there can be no suggestion of bad faith or improper purpose. *See, e.g., Minatec*, 2008 U.S. Dist. LEXIS 63802 at *26-*27 (finding nothing to support respondent's contention that petitioner was seeking information "with less than a good faith belief that § 1782 discovery would be helpful to the foreign tribunals and itself"); *In re Gemeinschaftspraxis*, 2006 U.S. Dist. LEXIS 94161 at *25-*26 ("Absent any indication of bad faith on [petitioner's] part, the Court is simply unwilling to weigh the request for § 1782 assistance itself as a negative discretionary factor."). This factor, therefore, also weighs in favor of granting Shire HGT's Application.

4. SHIRE HGT'S REQUESTS ARE NARROWLY TAILORED

Finally, district courts may consider whether the requested discovery is "unduly intrusive or burdensome." *Intel*, 542 U.S. at 265. In evaluating this factor, courts in this Circuit are "guided by Rules 26 and 45, which govern third-party discovery." *In re Gushlak*, 2011 U.S. Dist. LEXIS 91912 at *17. Under Federal Rule of Civil Procedure 26(b)(1), "parties are entitled to discovery regarding any nonprivileged matter that is relevant to any party's claim or defense, to the extent the requested is reasonably calculated to lead to the discovery of admissible evidence." *Id.* Similarly, under Federal Rule of Civil Procedure 45, whether a subpoena imposes an "undue burden" and must be quashed "depends upon such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Id.* at *19.

Here, Shire HGT's requests are narrowly tailored and present no undue burden to Mt. Sinai. Shire HGT seeks depositions of three professors who are currently employed by Mt. Sinai in New York and are the named inventors on the EP 189 patent that is the subject of the foreign proceedings where Shire HGT intends to use the requested testimony. This is precisely the type of discovery that ordinarily should be permitted under § 1782. *See John Deere Ltd. v. Sperry Corp.*, 754 F.2d 132, 137-138 (3d Cir. 1985) (reversing trial court's denial of § 1782 request for depositions of named inventor of patent at issue in foreign patent litigation and finding such testimony to be "material and equitable").

Because Shire HGT's request does not pose any undue burden or intrusion to Mt. Sinai, this factor also clearly weighs in favor of granting Shire HGT's Application.⁶

VII. CONCLUSION

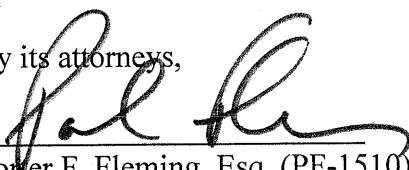
For the reasons set forth above, Shire HGT's Application should be granted.

Of counsel:

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SHIRE HGT, INC.,

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Date: March 16, 2012

⁶ Shire is willing to enter into an appropriate protective order with Mt. Sinai to eliminate any concerns they may have regarding the potential disclosure of confidential or proprietary information.

CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2012 this document was filed with the Court and that I caused a copy of this document to be served by hand on the following counsel:

General Counsel
Mount Sinai School of Medicine
One Gustave L. Levy Place
New York, N.Y. 10029-6574

A courtesy copy was also provided to counsel for Mt. Sinai by emailing a copy of the foregoing to the following attorneys:

Martin Weber
Jones Day
Prinzregentenstr. 11
80538 Munich
Federal Republic of Germany
(Tel.) +49.89.20.60.42.200
mweber@jonesday.com


Wilson Melendez

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the
Southern District of New York

In the Matter of the Application of Petitioner,
SHIRE HUMAN GENETIC THERAPIES, INC.
for an Order Pursuant to 28 U.S.C. § 1782 to
Take Discovery, Pursuant to the Federal Rules of
Civil Procedure, of Respondent MOUNT SINAI
SCHOOL OF MEDICINE and its employees,
ROBERT J. DESNICK, YIANNIS A. IOANNOU,
and DAVID F. BISHOP, For Use In Foreign
Proceedings

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Civil Action No.

(If the action is pending in another district, state where:
)

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Mt. Sinai School of Medicine
1425 Madison Avenue,
New York, New York 10029

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

See Schedule A, Attached

Place:	Frommer Lawrence & Haug LLP 745 Fifth Avenue New York, New York 10151	Date and Time:	TBD
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The deposition will be recorded by this method: stenographic, audio and/or audio-visual means

- ☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: _____

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk_____
Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party) Shire
, who issues or requests this subpoena, are:

Porter F. Fleming, Esq., Frommer, Lawrence & Haug LLP, 745 Fifth Avenue, New York, New York 10151,
pfleming@FLHlaw.com, 212-588-0800
5076050v1

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)**(c) Protecting a Person Subject to a Subpoena.**

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Schedule A

DEPOSITION TOPICS

1. The validity, scope and sufficiency of European Patent No. EP 1 942 189 B1, including but not limited to the structure of the α -galactosidase A isoforms that have been isolated from blood plasma and various other sources in the prior art.

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and DAVID F. BISHOP, For Use In Foreign
Proceedings

Civil Action No.

(If the action is pending in another district, state where:

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Robert J. Desnick, c/o Mt. Sinai School of Medicine
1425 Madison Avenue,
New York, New York 10029

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Frommer Lawrence & Haug LLP 745 Fifth Avenue New York, New York 10151	Date and Time:	TBD
--------	---	----------------	-----

The deposition will be recorded by this method: stenographic, audio and/or audio-visual means

- ☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: _____

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk_____
Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party) Shire
, who issues or requests this subpoena, are:

Porter F. Fleming, Esq., Frommer, Lawrence & Haug LLP, 745 Fifth Avenue, New York, New York 10151,
pfleming@FLHlaw.com, 212-588-0800

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____
_____.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)**(c) Protecting a Person Subject to a Subpoena.**

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

Schedule A

DEPOSITION TOPICS

1. The validity, scope and sufficiency of European Patent No. EP 1 942 189 B1, including but not limited to the structure of the α -galactosidase A isoforms that have been isolated from blood plasma and various other sources in the prior art.

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the
Southern District of New York

In the Matter of the Application of Petitioner,
SHIRE HUMAN GENETIC THERAPIES, INC.
for an Order Pursuant to 28 U.S.C. § 1782 to
Take Discovery, Pursuant to the Federal Rules of
Civil Procedure, of Respondent MOUNT SINAI
SCHOOL OF MEDICINE and its employees,
ROBERT J. DESNICK, YIANNIS A. IOANNOU,
and DAVID F. BISHOP, For Use In Foreign
Proceedings

Civil Action No.

(If the action is pending in another district, state where:)

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Yiannis A. Ioannou, c/o Mt. Sinai School of Medicine
1425 Madison Avenue,
New York, New York 10029

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Frommer Lawrence & Haug LLP 745 Fifth Avenue New York, New York 10151	Date and Time:	TBD
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The deposition will be recorded by this method: stenographic, audio and/or audio-visual means

- ☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: _____
CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party) Shire, who issues or requests this subpoena, are:

Porter F. Fleming, Esq., Frommer, Lawrence & Haug LLP, 745 Fifth Avenue, New York, New York 10151,
pfleming@FLHlaw.com, 212-588-0800

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____
_____.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____
_____ *Server's signature*

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)**(c) Protecting a Person Subject to a Subpoena.**

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

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(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

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(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

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(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

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Civil Action No.

(If the action is pending in another district, state where:

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Schedule A

DEPOSITION TOPICS

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